EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
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Committee for Medicinal Products for Human Use (CHMP)

Neulasta

International non-proprietary name: pegfilgrastim

Procedure No: EMEA/H/C/000420/PSUV/0071

Period covered by the PSUR: 01.02.2010 - 31.01.2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Neulasta, the scientific conclusions of PRAC are as follows:

Given the similar mechanism of action of Neulasta (pegfilgrastim) and filgrastim on the one hand, and the narrow indication for Neulasta compared to the indications granted for filgrastim on the other hand, off-label use constitutes a potential risk for Neulasta. The PRAC considered important to be able to trace the exact granulocyte-colony stimulating factors (G-CSF) used in treating patients for monitoring off-label use and assessing potential adverse events. Therefore, in line with other products in the same class, the PRAC considered that changes to the product information were warranted to include a statement to improve the traceability of granulocyte-colony stimulating factors.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Neulasta the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance pegfilgrastim is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.